

1K123545

FEB 01 2013

**510(k) Summary
for
Sirona Dental Systems
inCoris TZI**

1. Sponsor

Sirona Dental Systems GmbH

Fabrikstrasse 31

D-64625 Bensheim

Germany

Contact Person: Fritz Kolle

Telephone: +49 6251 16 3294

Date Prepared: November 16, 2012

2. Device Name

Proprietary Name: inCoris TZI

Common/Usual Name: Powder, Porcelain

Classification Name: Porcelain powder for clinical use

3. Predicate Devices

Glidewell's PrismaTM Clinical Zirconia (PrismaTM CZ) (K060104)

4. Intended Use

Classic and Speed Sintering:

Fully anatomic crowns and bridges in the posterior and anterior tooth region. Bridges with max. two pontics.

Super Speed Sintering:

Fully anatomic crowns.

5. Device Description and Function

The inCoris TZI are blocks of various sizes from which custom made dental restorations are grinded using Sirona CAD/CAM system. inCoris TZI ceramics constitute blocks comprised of zirconia ceramics (ZrO_2). The blocks are initially manufactured in a partially sintered state; then, they are individually processed to specification, and finally, densely sintered. One end plane of a block is mounted to a metal carrier that is inserted in the spindle's clamping chuck of the grinding machine. Grinded restorations are colored by dipping the restoration in color liquid prior final sintering.

6. Scientific Concept

The underlying scientific concept is

- Processing dental restorations by Sirona Dental CAD/CAM System
- Restorations are grinded from an inCoris TZI block by a Sirona CAM machine
- Different sintering time to gain appropriate material properties

7. Physical and Performance Characteristics

7.1. Design

The design of the inCoris TZI is described in section 5, Device Description and Function.

7.2. Material Used

inCoris TZI ceramics constitute blocks comprised of zirconia ceramics (ZrO_2). One end plane of a block is mounted to a metal carrier that is inserted in the spindle's clamping chuck of the grinding machine. The material is biocompatible according to ISO 10993-1: 2009, "Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process".

7.3. Physical Properties

Final technical data of densely sintered inCoris TZI.

Density:	6.08 g cm^{-3}
Fracture toughness K_{IC}	$6.4 \text{ MPa m}^{1/2}$
Thermal expansion coefficient (20 - 500 °C):	$10.4 \cdot 10^{-6} \text{ K}^{-1}$
Bending strength:	$> 900 \text{ MPa}$

7.4. Chemical Properties

Component	inCoris TZI ¹⁾
ZrO ₂ +HfO ₂ +Y ₂ O ₃	≥ 99.9%
Y ₂ O ₃	5.4%
Al ₂ O ₃	≤ 0.35%
Fe ₂ O ₃	≤ 0.01%
Other oxides	≤ 0.2%

¹⁾Values of colored restorations.

8. Summary of the technological characteristics

Sirona inCoris TZI and Glidewell's PrismaTM Clinical Zirconia (PrismaTM CZ) are made of zirconia ceramics (ZrO₂). inCoris TZI is block shaped whereas Glidewell's PrismaTM Clinical Zirconia is disk shaped.

Both devices meet ISO 6872: 2008, "Dentistry -- Ceramic materials" and ISO 13356: 2008, "Implants for surgery, Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)". Physical and chemical properties are similar.

9. Nonclinical Testing

Sintering tests have been performed which show that the mechanical properties are appropriate for the indications for use.

10. Clinical Testing

Clinical tests have not been performed.

11. Conclusion

Based on the comparison of intended use, indications, contra-indications, material properties and processing/fabrication, Sirona Dental Systems believes that the InCoris TZI blocks are substantially equivalent to Glidewell's PrismaTM Clinical Zirconia (PrismaTM CZ) (K060104).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

February 1, 2013

Mr. Fritz Kolle
Quality Management/Regulatory Affairs
Sirona Dental Systems, GmbH
Fabrikstrasse 31
Bensheim
Germany D-64625

Re: K123545
Trade/Device Name: inCoris TZI
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Codes: EIH
Dated: November 16, 2012
Received: November 21, 2012

Dear Mr. Kolle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

K123545

Device Name: inCoris TZI

Indications for Use:

Classic and Speed Sintering:

Fully anatomic crowns and bridges in the posterior and anterior tooth region.
Bridges with max. two pontics.

Super Speed Sintering:

Fully anatomic crowns.

Prescription Use X
(Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen
2013.02.01 08:55:20 -05'00'

~~Sirona Dental Systems~~ 510(k)

November 16, 2012

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K123.545